

REMARKS***Claim Rejections under 35 U.S.C. § 112***

Claims 32 and 75-79 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Generally, with respect to claim 32, the examiner asserts that the language "substantially continuous contact with a surface of¹ another winding for a complete turn of the given winding" lacks original support from the specification. Paper No. 20070131, page 2. Specifically, the examiner asserts that Figures 1, 8, and 10 only show a small portion of the whole ring and that these figures are merely sketches that lack the clarity and precision of a photograph or drawings drawn to scale. This, however, appears to be a heightened standard as photographs are not ordinarily permitted in utility patent applications. MPEP § 608.02. In fact, in a written description inquiry, the question is whether the specification conveys with *reasonable clarity* to those skilled in the art that the inventor was in possession (as of the filing date of the application) of the invention now claimed. MPEP § 2163. Possession of an invention claimed is shown by describing the claimed invention with all of its limitations using such descriptive means as *words, structures, figures, diagrams, and formulas*. See MPEP § 2163(I); 2163.02. Notably, photographs and to-scale drawings are not required to convey possession to a skilled artisan with reasonable clarity. Furthermore, the subject matter of the claim need not be described literally to satisfy the written description requirement. See MPEP § 2163(I)(B); 2163.02. It is respectfully submitted that the specification, including the figures, shows with reasonable clarity that the inventor had possession of the claimed invention at the time the application was filed.

Claim 32 calls for a second annular element comprising a bundle of radially overlapping windings formed of a strand of resilient wire, a given winding having substantially continuous contact with another winding for a complete turn of the given winding. A resilient clamping ring 30 is shown in Figures 1, 8, and 10. In an embodiment, the clamping ring 30 is formed of a plurality of coils 32 of resilient wire. See, e.g., specification at page 7, lines 6-26. The ring 30 may be formed by wrapping a single length of wire around a mandrel having a central axis "C" and then securing the coils 32 into a bundle using ties 34. *Id.*, Fig.1. There is nothing in this description to suggest that one portion of the ring 30 is substantially different from another

¹ This phrase has been deleted from claim 32 in a prior response to Office action.

portion of the ring 30. Thus, even though a portion of the ring 30 is shown in Figure 8, this portion does not appreciably differ from any other portion of the ring 30.

There are about 8-10 coils 32 shown in Figures 8 and 10. But the number of coils 32 can be varied; in some embodiments, there may be as few as two coils and in other embodiments there may be as many as 100 or more. Specification, page 7, lines 20-26. It is respectfully submitted that in an embodiment of the clamping ring 30 having a two coils, which is formed as described above, one coil is in substantially continuous contact with the other coil for a complete turn of the clamping ring 30. *See, e.g.*, Figures 1, 8, and 10. There is no reason why the same would not be true for an embodiment with greater than two coils. For example, Figure 10 shows a cross-section of the clamping ring 30, which is taken generally along line 10-10 of Figure 8. Each coil in the cross section contacts at least one other coil, coils toward the center of the bundle can contact four or more other coils. As the coils are all wrapped around a mandrel and secured into a bundle with ties and each coil contacts at least one other coil, it is respectfully submitted that the specification conveys with reasonable clarity to a skilled artisan that a given winding has substantially continuous contact with another winding for a complete turn of the given winding. Thus, the examiner is requested to reconsider the § 112 rejection of claims 32 and 75-79.

Furthermore, as claim 32 is not rejected over a prior art reference, claim 32 is now in condition for allowance.

Claims 67-69 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. As the rejection cites to language that is not in the claim, the rejection is believed to be improper.

Although not rejected, claim 75 was objected to due to language that the examiner asserts is confusing. In view of the explanation given above, the examiner is request to reconsider his objection.

Double Patenting

Claims 32, 65, 66, and 69 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 58, 48, 48, and 7 respectively of copending application 10/832,159. Although the applicant does not necessarily agree with the examiner's rejection, the applicant notes that upon receipt of an indication of allowance, a terminal disclaimer may be filed to overcome any sustainable double-patenting rejection.

Claim Rejections—35 U.S.C. § 102

Claims 67, 68, 70-73, 75-79, and 81-82 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Dwyer (US 5,843,167) and claims 65, 66, and 69 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Sigwart (5,443,500). To anticipate, every element of a claim must be found in a single prior art reference as set forth in the claim. *See, e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628,631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). That is, the identical invention must be shown in as complete detail as is contained in the claim. *See, e.g., Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989).

1. Claims 70-73

It is respectfully submitted that the examiner has not established *prima facie* anticipation for claims 70-73. Specifically, the examiner has not established that Dwyer's graft extends along a length of a first blood vessel and that *a part of the graft is adapted to be positioned past* a point of an intersection of the first blood vessel and a second blood vessel so as not to occlude an opening to permit communication of the intersection as is called for in claim 70.

In the Office action, the examiner asserts that the Dwyer stent-graft is placed entirely past an intersection except for the bends (*e.g.* of the anchor 14R) extending beyond the graft to meet the intended use functional language of the claim. Paper No. 20070131, page 7. It is respectfully submitted that the language of claim 70 italicized above recites a positive structure that is not found in Dwyer. If an element of a claim is "adapted to" do something, this language can impart a structural limitation on the element. *See In re Venezia*, 530 F.2d 956, 959, 198 U.S.P.Q. 149 (CCPA 1976).

For example, the court in *Venezia* explained that claim language such as "a pair of sleeves...each sleeve of said pair *adapted to be fitted* over the insulating jacket of one of said cables" imparts a structural limitation to the sleeve; each sleeve is structured or dimensioned so that it can be fitted over the insulating jacket of the cable. *See In re Venezia*, 530 F.2d 956, 959, 198 U.S.P.Q. 149 (CCPA 1976) (emphasis added). Similarly, language such as "*when said housing is in its repositioned location*" also limits structure. *Id.* That is, this language defines a present structure or attribute of the housing that limits the structure of the housing to those configurations that allow for the completed assembly. *Id.* In contrast, language such as "being crimpable onto a shield means" and "when said member is crimped onto a shield" does not

positively recite a structural relationship between the two elements in question. *Id.* That is, this language describes activities that may or may not occur. *Id.* at 960.

Like the claim language in *Venezia*, the language of claim 70 imparts structural limitations. For instance, as is indicated by claim 70, the graft is to extend along a length of a first blood vessel and a part of the graft is adapted to, or is structured or dimensioned to, be positioned past a point of intersection of the first blood vessel and a second blood vessel so as not to occlude an opening to permit communication of the intersection when a folded ring (which is attached to the graft) is engaged with a body passage. Thus, present structural attributes of the graft-ring combination later allow the positioning claimed in claim 70 to be effected. Dwyer's stent-graft has no such structure.

For example, Dwyer has two anchors 14R and 14I that are attached to the ends of a graft. The anchors 14R and 14I have a zigzag pattern with alternating iliac (proximal) and renal (distal) bends 20I and 20R respectively. Column 7, lines 42-48 (according to Dwyer "distal" refers to directions that are toward the patient or in a renal direction and "proximal" refers to directions that are toward the physician or in an iliac direction. Column 7, lines 1-9); Figure 2. Referring to Figures 6 and 7 of Dwyer, only a proximal portion of the anchor 14R, which includes the iliac bends, contacts the graft. Most abdominal aortic aneurisms occur between the renal arteries and the branching of the aorta into the iliac arteries. Thus, if the renal bends (or iliac bends) of Dwyer's ring 14R were to be positioned past the intersection of the abdominal aorta 48 and the renal arteries (not shown in Figure 6), the graft would block the intersection of the two vessels. Thus, the structure of Dwyer's graft-anchor combination does not permit the graft to extend along the length of the aorta and to be positioned *past* a point of an intersection of the aorta and the renal arteries without occluding the intersection. In other words, Dwyer's graft-anchor combination cannot be inserted in a femoral artery for permanent positioning in the abdominal aorta *past* the point of intersection of the abdominal aorta and the renal arteries without blocking the intersection. The structure of Dwyer's endoprosthesis permits positioning only on the side of the intersection in which the aneurism is located. *See, e.g.*, column 18, lines 9-34. For at least these reasons, Dwyer does not show a prosthesis that is identical to that of claim 70 in as complete detail as is contained in claim 70—Dwyer does not anticipate.

If the examiner does not consider the language of claim 70 to impart present structural limitations, which it does, Dwyer still does not anticipate. Namely, Dwyer does not describe any

portion of his endoprosthesis as being adapted to be positioned *past* a point of intersection of the aorta and the renal arteries. For example, to deliver Dwyer's endoprosthesis a physician first advances a delivery device through a patient's femoral artery and ends delivery in the abdominal aorta. After the physician permanently positions the endoprosthesis in the abdominal aorta, the renal anchor 14R is located *on the renal side* of the aneurism. Column 18, lines 17-22; Figure 6. In other words, the anchor 14R is distal, or toward the renal direction. Column 7, lines 1-9. Thus, Dwyer does not show that his graft extends along the length of the abdominal aorta or that it is positioned past a point of intersection of the aorta and the renal arteries without occluding the intersection. Simply, Dwyer does not describe his endoprosthesis in such detail to show that it is identical to the prosthesis of claim 70—Dwyer does not anticipate.

Dwyer does not describe such a positioning of his endoprosthesis because his endoprosthesis cannot be positioned as claimed. For example, in the paragraphs above, it is explained in general terms that a physician cannot permanently position Dwyer's endoprosthesis past a point of intersection of the abdominal aorta and the renal arteries without the graft occluding the intersection. This is especially true of the embodiment of Dwyer's anchor 14R that the examiner relies on to reject claim 70. For example, referring to Figures 35-38, the distal anchor 14R includes a hook assembly 142 attached to the distal bends 20R. The hook assembly 142 includes a torsion spring 144, a shank 148, and a hook tip at the end of the shank 148. Column 16, lines 36-55. The hooks must protrude radially outwardly of the remaining portions of the anchor and the spring 144 biases the shank 148 and tip in a configuration in which the tip is angled slightly downward. *Id.* See also Column 2, lines 60-61. The device shown in Figures 35-38 is dimensioned and constructed to engage the tissue 154.

Given the specifics of this embodiment of Dwyer's anchor 14R, it is respectfully submitted that an endoprosthesis including this embodiment of an anchor is particularly ill suited to be permanently positioned past a point of intersection of the aorta and the renal arteries without obstructing the intersection. For example, if the hooks at the ends of the shanks 148 engaged the abdominal aorta past the intersection of the abdominal aorta and the renal arteries, the distal bends 20R would be even more distally located (*e.g.* toward the patient) than the hooks. See, *e.g.*, Figures 6 and 38. In other words, the hooks are "proximal" or toward the physician with respect to the distal bends, which causes the graft to be relatively close to the hooks. Because the graft is close to the hooks in this embodiment, blockage of the intersection

by the graft even more certain. *See, e.g.*, Figure 6. Thus, even if the structural limitations of claim 70 were to be (wrongly) considered intended use functional limitations, the examiner has not shown that the embodiment of Dwyer that he relies upon can indeed meet the alleged functional language. Accordingly, *prima facie* anticipation has not been established. Reconsideration of the rejection is requested.

2. Claims 81 and 82

For at least the reasons expressed above in section 1, it is respectfully submitted that the examiner has not established *prima facie* anticipation for claims 81 and 82.

Additionally, with respect to claim 81, the claim language is even more specific. That is, pursuant to claim 81 the *graft is adapted to be positioned* within a first blood vessel (*e.g.* the aorta), proximate a second blood vessel (*e.g.* the renal arteries) such that the diametric axis of an annular element (that is attached to the graft) is proximate to an intersection of the first and second blood vessels. Furthermore, a part of the graft is to extend past the intersection so as not to occlude an opening and to permit communication of the intersection, and *only* a part of *both* of the graft and the annular element engages a portion of the first blood vessel located past the second blood vessel. Based on the explanation of Dwyer given above with respect to claim 70, it is clear that Dwyer's endoprosthesis does not have a structure that shows the prosthesis of claim 81 in as complete detail as is contained in claim 81. Reconsideration of the rejection is requested.

With respect to claim 82, and based on the explanations given above, clearly Dwyer's anchor 14R is not adapted to be folded around its diametric axis and to resiliently engage a first human blood vessel in a C-shaped deformed configuration, a part of the C-shaped deformed element to resiliently engage the first human blood vessel past a point of intersection of the first blood vessel and a second blood vessel to permit communication of the intersection. Thus, reconsideration of the rejection is requested.

3. Claims 75-79

Claim 75 recites, an annular element adapted to be folded around its diametric axis...the element attached to an end of a graft, a tip of *each fold* of the folded element *to contact the graft*. It is respectfully submitted not every element of claim 75 is found in Dwyer as set forth in the claim.

As is explained above, the basic structure of Dwyer's anchor has a zigzag pattern with alternating iliac and renal bends 20I and 20R respectively. Column 7, lines 43-46. The renal

bends 20R of Dwyer's ring 14R that do not contact the graft. *See, e.g.*, Figures 6 and 7. Clearly, *each bend* in Dwyer's anchor 14R does not contact a graft.

The examiner asserts, however, that the diametrical axis (of Dwyer's anchor 14R) can be taken with the graft portion of Dwyer's ring (*e.g.*, proximally on the anchor 14R) such that each fold of the axis is in contact with the graft. Paper No. 20070131, page 7. But claim 75 calls for a tip of *each* fold of a folded element to contact the graft. As half of the bends in Dwyer's anchor 14R do not contact the graft, Dwyer does not anticipate claim 75.

4. Claims 67 and 68

Claim 67 recites a ring having a diameter and comprising windings formed of a single strand of resilient metal wire, the diameter of the ring substantially the same as a diameter of at least one of the windings. Clearly, Dwyer's springs 144 do not have a diameter that is substantially the same as the diameter of the anchor 14R. *See* Figure 35.

In the Office action, the examiner asserts that the type of diameter of the windings is not specified and that it can be taken across a plurality of windings on opposite sides of the ring. Paper No. 20070131, page 7. It is respectfully submitted that if the value representing the diameter of each spring 144 shown in Figure 35 were added together, this still would not equal the diameter of the anchor 14R. For instance, the diameter of the anchor 14R wire is 0.014". Column 7, lines 42-43. Thus, the innermost diameter of the springs 144 is 0.014 inches. Furthermore, the expanded diameter of the anchor is 14-26 mm. Column 8, lines 2-6. If 0.014 is multiplied by 6 (the number of springs shown in Figure 35) then the combined diameter of the springs 144 is 0.084 inches. This number converts to 2.13 mm, which is not substantially the same as 14-26 mm. Thus, the value for the combined diameters of the springs 144 is much less than the value for the diameter of the expanded anchor—they are not substantially the same. Accordingly, Dwyer does not anticipate.

This same reasoning may also be applied to other claims with like language in further support of the lack of anticipation by Dwyer.

Claim 67 also calls for the windings to be wound one over the other and connected together to form a bundle, the bundle of the windings having a substantially circular cross-section, the cross-section taken through any portion of the ring along a line that is parallel to the longitudinal axis (of a graft) such that *no matter where the cross-section is taken on the ring*, the cross section of the windings is substantially circular. In contrast, a cross section can be taken

through portions of Dwyer's anchor 14R that does not intersect the springs 144; Dwyer's springs 144 are found at only the distal bends of the anchor 14R. *See* Figure 35. Therefore, a cross-section can only be taken through certain locations on the anchor 14R that will also be through springs 144. For at least these additional reasons, Dwyer does not anticipate claim 67.

5. Claims 65, 66, and 69

In the Office action, the examiner asserts that Sigwart as evidenced by Porier anticipates claims 65 and 66. *See* Paper No 2007 0131, page 6. Claim 66 recites the ring formed of a bundle of windings of a strand of resilient metal wire and claim 66 recites a single strand of resilient metal wire. In Appeal No. 2001-1407 decided on September 13, 2002, the Board defined wire as "a metal in the form of a flexible thread or slender rod." Appeal No. 2001-1407, page 6.

Based on this definition, Sigwart does not disclose a ring formed of a strand of resilient metal wire. For example, Sigwart uses a flat rectangular *sheet* of biocompatible, malleable material. Column 3, lines 6-9. The rectangular sheet may be plain or perforated. Column 2, line 1. Because Sigwart's flat rectangular sheet does not meet the definition of wire as defined (in this case) by the Board, Sigwart does not anticipate claims 65 and 66.

MISCELLANEOUS

Copending Applications

A list of the copending applications is provided below. The examiner is requested to refer to the image file wrapper for the 10/832,159, 11/205,826, and 11/496,126 applications to view the claims.


1. Serial No. 10/832,159, filed April 26, 2004, which is a divisional of 09/365,860, filed August 3, 1999 (now issued), which is a continuation of this application.
2. Serial No. 11/205,826, filed August 17, 2005, which is a continuation of application 10/124,944, filed April 18, 2002 (now issued), which is a divisional of this application.
3. Serial No. 11/496,162, filed July 31, 2006, which is a continuation of application 10/118,409, filed April 8, 2002 (now issued), which is a continuation of this application.

CONCLUSION

In view of remarks herein, the examiner is requested to reconsider each of the rejections so that the application can pass to issue. The examiner's prompt action in accordance therewith is respectfully requested. The commissioner is authorized to charge any additional fees, including extension of time fees, or credit any overpayment to Deposit Account No. 20-1504 (VAS.0002US).

Respectfully submitted,

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